

DEA/HHS Telemedicine Prescribing of Controlled Substances Extension

November 21, 2024

On November 15, 2024, the US Drug Enforcement Agency (DEA) and the Department of Health and Human Services (HHS) jointly issued a temporary rule, which extends the current flexibilities relating to prescribing controlled substances via telemedicine through December 31, 2025. See the temporary rule.

Without this action, the telemedicine flexibilities were scheduled to expire at the end of the year, on December 31, 2024. Per the DEA's press release, the agencies are extending the flexibilities to continue to review and consider the 38,000 comments and feedback received from public listening sessions in response to the 2023 proposed telemedicine rules.

This marks the third extension of the DEA's temporary rule, which was originally enacted in 2020, during the height of the COVID-19 pandemic. The DEA's rule created certain flexibilities to the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act) – the federal law that governs telemedicine prescribing of controlled substances. These exceptions include:

1. Allowing qualified practitioners to prescribe Schedule II – V controlled substances via audio-video telemedicine without conducting a prior in-person medical examination of the patient, subject to certain requirements.
2. Authorizing qualified practitioners to prescribe Schedule III – V narcotic controlled medications approved by the Food and Drug Administration (FDA) for treatment of opioid use disorder via audio-only telemedicine encounters (e.g., buprenorphine).
3. Allowing a qualified practitioner to register with the DEA in one state, instead of requiring the practitioner to register with the DEA in each state the practitioner seeks to prescribe.

These flexibilities allow practitioners and digital health companies that treat patients with controlled substances to expand their scope of operations by removing the in-person requirement (at least on the federal level), which served as a barrier to a digital-only offering.

The timing of the extension further punts the enactment of the long-awaited permanent regulations interpreting the federal Ryan Haight Act to the incoming Trump administration, which will be forced to act on this issue in its first year. Digital health companies whose offerings include controlled substance prescribing should stay abreast of any future changes to maintain compliance.

If you have any questions or would like further information about what this may mean for your business, please reach out to a member of Cooley's life sciences and healthcare regulatory team.

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